**NxStage Medical, Inc.**
**NxStage PureFlow SL**
**Special 510(k) Device Modification**

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92.

**A. Submitter's Information:**

| | |
|---|---|
| **Date** | March 5, 2014 |
| **Name:** | NxStage Medical, Inc. |
| **Address:** | 350 Merrimack Street<br>Lawrence, MA 01843 |
| **FDA Establishment Owner/Operator Number:** | 9045797 |
| **Contact Person:** | Mary Lou Stroumbos<br>Director, Regulatory Affairs |
| **Phone:** | (978) 687-4872 |
| **Fax:** | (978) 687-4750 |
| **Manufacturer:** | MEDIMEXICO, S. DE R.L. DE C.V.<br>Av. Valle imperial No. 10523<br>Parque industrial Valle Sur<br>Tijuana, B.C., Mexico 22180 |
| **FDA Establishment Registration Number:** | 9616074 |
| **Sterilization Site:** | Steris Isomedix, Inc.<br>1000 S. Sarah Place<br>Ontario, CA 91761<br><br>Contract Sterilizer |

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**B. Device Name:**

| | |
|---|---|
| **Trade/Proprietary Name:** | NxStage PureFlow SL |
| **Common/Usual Name:** | Subsystem, proportioning |
| **Classification Name:** | Hemodialysis systems and accessories |
| **Regulation Number:** | 21 CFR 876.5820 |
| **Product Code:** | 78 FKR |
| **Device Classification:** | Class II |
| **Device Panel:** | Gastroenterology-Urology (GU)/ Gastro-Renal (GRDB) |

**C. Substantial Equivalence:**

This submission is a Special 510(k) Device Modification as described in the FDA's Guidance document entitled, "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this Special 510(k), NxStage has provided certification of compliance to 21 CFR §820.30 Design Control Requirements. Design validation testing was performed to ensure that the NxStage PureFlow SL (PFSL) module with modifications meets design specifications. The NxStage PFSL module with modifications has been compared to the legally marketed predicate device as cleared through K111174 (September 19, 2011) and was found to be substantially equivalent.

**D. Device Description/Indications for Use:**

The NxStage PureFlow SL module is an optional accessory to the NxStage System One used to prepare water for hemodialysis that meets ANSI/AAMI/ISO 13959:2009 and proportion it with dialysate concentrate to produce dialysate per ANSI/AAMI/ISO 11663:2009. The PureFlow SL consists of the Control Unit (CU), the water Pre-Treatment Unit, the optional OPTA Kit, the Purification Pack (PAK), and the Dialysate Sack (SAK) with Dialysate Concentrate.

**Indications for use:**
The NxStage PureFlow SL module is an optional accessory to the NxStage System One that prepares dialysate for use during hemodialysis, as prescribed by the physician.

**E. Technological Characteristics:**
The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate device.

**Table 1**
**Device Technological Characteristics Comparison Table**

| *Feature* | Proposed NxStage PFSL Module (subject of this 510(k)) | NxStage PFSL Module (K111174) |
|---|---|---|
| *Indication for Use* | Same | The NxStage PureFlow SL module is an optional accessory to the NxStage System One that prepares dialysate for use during hemodialysis, as prescribed by the physician. |
| **Water Purification** | | |
| *Water purification technology* | Same | Deionization |
| *Ultrafiltration* | Same | Redundant ultrafiltration replaced within 12- weeks |
| *Water Quality* | Same | Meets or exceeds requirements per ANSI/AAMI/ISO 26722:2009 Water treatment equipment for hemodialysis applications |
| **Dialysate Proportioning** | | |
| *Proportioning method* | Same | Mixed to use Batch via volumetric dosing of purified water with specified amount of electrolyte concentrate |

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| Table 1<br>Device Technological Characteristics Comparison Table | | |
|---|---|---|
| ***Feature*** | **Proposed NxStage PFSL Module (subject of this 510(k))** | **NxStage PFSL Module (K111174)** |
| *Conductivity Measurement* | Same | Yes – the System measures final batch conductivity prior to each treatment per ANSI/AAMI/ISO 26722:2009 |
| **Concentrate** | | |
| *Dialysate Concentrate* | Same | Standard hemodialysis concentrate per ANSI/AAMI/ISO 13958:2009 |
| *Packaging* | Same | Packaged in flexible LLDPE bags with standard luer lock connector. Ranging in size from 20L to 60L |
| *Buffer* | Same | Lactate |
| **Point of Use Dialysate Quality** | | |
| *Mix-to-Use Time* | Same | 96-hours |
| *Bioburden* | Same | AAMI/ANSI/ISO 11663: <100 CFU/ml |
| *Endotoxin* | Same | AAMI/ANSI/ISO 11663: <0.5 EU/ml |
| *Batch size* | Same | Range – 20 to 60 L<br>(40, 50 and 60L currently available) |
| **Fluid warming** | | |
| *Method* | Same | Integrated fluid warming pad |

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**F. Summary of Non-Clinical Test/Performance Testing - Bench**

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed NxStage PureFlow SL is substantially equivalent to the predicate device and is suitable for the labeled indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

NxStage Medical, Inc.
Mary Lou Stroumbos
Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K140571
Trade/Device Name: NxStage® PureFlow™ SL
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FKR
Dated: April 17, 2014
Received: April 18, 2014

Dear Mary Lou Stroumbos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K140571

Device Name: NxStage® PureFlow™ SL

*Indications for Use:* The NxStage PureFlow SL module is an optional accessory to the NxStage System One™ that prepares dialysate for use during hemodialysis, as prescribed by the physician.

**Prescription Use** ___X___ **AND/OR** **Over-The-Counter Use**_____
**(Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Herbert P. Lerner -S
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